



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,677	03/30/2000	NORITAKA II	Q58580	3130

7590 01/13/2004

SUGHRUE MION ZINN
MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20037

EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,677

Applicant(s)

II ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,20 and 31-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,20 and 31-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1617

DETAILED ACTION

Applicant's amendments filed July 29, 2003 have been entered. Claims 19-20 and 31-54 are pending.

Applicant's declaration filed August 4, 2003 have been considered. The outstanding rejection under 35 USC 112, first paragraph and objection to the specification with regard to new matter are withdrawn in view of the declaration filed August 4, 2003.

The outstanding rejections under 35 USC 112, first paragraph and second paragraph with regard to enablement are withdrawn in view of the amendments filed July 29, 2003.

The outstanding rejections under 35 USC 102 are withdrawn in view of the amendments filed July 29, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-20 and 31-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearmain (US Patent 5,188,839) in view of Hoshino (WO 97/12606, English equivalent, US Patent 6,146,661, is also provided).

Art Unit: 1617

Pearmain teaches cimetidine tablet, which improve palatability, that consists essentially of a pH adjusting agents: sodium bicarbonate, a sugar alcohol: sorbitol and a sweetener: aspartame (See particularly the abstract, col.4, example 3). Pearmain also teaches the ratio between sorbitol and cimetidine is about 3.5 to 1; the ratio between sodium bicarbonate and cimetidine is about 0.9 to 1 (See particularly col. 4, example 3).

Pearmain does not expressly teach that erythritol, the sugar alcohol, is in the cimetidine tablet. Pearmain does not expressly teach that the ratio between the sugar alcohol to cimetidine is from 5 to 10 : 1. Pearmain does not expressly teach that the pH values of the solution of the pH adjusting agent be equal to or higher than that of the solution of cimetidine. Pearmain does not expressly teach a method of masking the taste of an oral preparation employing the cimetidine tablet with improved palatability. Pearmain does not expressly teach the specific sugar alcohol amount.

Hoshino teaches a chewable tablet which may contain a H₂ receptor blocking agent including cimetidine and erythritol (See abstract, claim 1). Hoshino also teaches a method of improving the unpleasant taste of the tablet with sugar alcohol herein, including erythritol (See col. 1, lines 51-58; col. 2, lines 25-56 particularly, and col. 6, line 1 to 60).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employ the sugar alcohol, erythritol in the cimetidine tablet of Pearmain, with the ratio between the sugar alcohol to cimetidine being from 5 to 10 : 1 and the pH values of the solution of the pH adjusting agent be equal to or higher than that of the solution of cimetidine. It would have been obvious to one of ordinary skill in

Art Unit: 1617

the art at the time the invention was made to adjust the amount of sugar alcohol employed.

One of ordinary skill in the art would have been motivated to incorporate erythritol into the cimetidine tablet of Pearmain because it is known in the art that erythritol is useful to improve from unpleasant intrabuccal (oral) sensation in chewable tablet compositions. The incorporation of erythritol to improve the taste of a cimetidine tablet is therefore *prima facie* obvious. Optimization of result effect parameters (i.e., ingredient amounts, solutions, or suspension, pH values) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Response to Arguments

Applicant's remarks filed July 29, 2003 regarding Hoshino teaching a method of improving intrabuccal sensations (e.g., discomfort such as roughness or dustiness in the mouth) and therefore no motivation or suggestion being provided to combine the teaching of cited prior arts to arrive at the claimed invention have been considered. The remarks are not found persuasive because the combined teaching of Pearmain and Hoshino clearly renders the claims herein obvious because employing the ingredients herein (i.e., sugar alcohol, pH adjusting agent, and sweetener) would have been reasonably expected to be useful in formulating a better palatable oral administration preparation. Substituting any well-known sugar alcohol, including erythritol, into Pearmain's composition would have been considered obvious as selecting from the obvious alternatives. Furthermore, using the sugar alcohols taught by Hoshino, such as

Art Unit: 1617

erythritol, would have been reasonably expected to have an additional advantage of improving intrabuccal sensation. Moreover, Hoshino teaches that intrabuccal sensation includes, but not limit to, discomfort such as roughness or dustiness in the mouth.

Hoshino teaches the employment of sugar alcohol, a commonly known sweetner (See Hoshino col. 2, line 65), to improve the intrabuccal sensation of a cimetidine oral dosage form. Therefore, employing sugar alcohol herein would have been reasonably expected to improve the roughness or dustiness and taste of the same at the same time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-

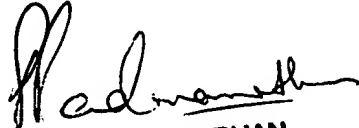
Art Unit: 1617

1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
Patent Examiner
Art Unit 1617


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER
1/12/04